

REMARKS

Claims 20, 23-29 and 31-39 are pending in this application and have been objected to or rejected as obvious. In response to the Office Action of December 8, 2009, Applicants have amended claims 20, 31 and 35, and the specification. In view of these amendments and the remarks below, Applicants respectfully request that the objection and rejection be reconsidered and withdrawn.

I. OBJECTION TO CLAIM 25

The Examiner has objected to claim 25 as not being supported by the specification, and suggests amending the specification to recite that the liquid containing means has a volume of less than 10 cc in light of the fact that this limitation was originally disclosed in the claims as filed with the application. Applicants have amended the specification accordingly, and therefore respectfully request that this objection be withdrawn.

II. REJECTION OF CLAIMS 20, 22-28, 31, 35 AND 36

Claims 20, 23-28, 31, 35 and 36 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of the combination of Ayre¹, Mendoza² and Suzuki³.

A. THE RECITED INVENTION

Claim 20 is directed to a sampler for taking a sample from a body cavity. The sampler has a tubular means adapted to be introduced in said cavity. A storage means is connected to the tubular means. A vacuum means is connected to the storage means and/or the tubular means. Claim 20 has been amended to recite that the tubular means has a rigid tube with a fixed outer diameter of at least 1 cm and a curved introduction end. The rigid tube provides a closure in the body cavity. There are a number of sampling openings provided only at the curved introduction end. One of these openings is a central opening having a diameter of less than 5 mm. The sampler further has a liquid containing means and a pump means. The liquid containing means contains a flushing solution, which is expelled

¹ United States Patent Number 3,540,432 to Ayre ("Ayre").

² United States Patent Number 6,071,231 to Mendoza *et al.* ("Mendoza").

³ United States Patent Number 4,781,699 to Suzuki *et al.* ("Suzuki").

through the curved introduction end by the pump means. Claims 23-28 depend from claim 20.

Claim 31 is directed to a sampler assembly that includes a sampler for taking a sample from a body cavity. The sampler has a tubular means adapted to be introduced in the cavity. A storage means is connected to the tubular means. A vacuum means is connected to the storage means and/or the tubular means. Like claim 20, claim 31 has been amended to recite that the tubular means has a rigid tube with a fixed outer diameter of at least 1 cm and a curved introduction end. A number of sampling openings are provided only at the curved introduction end. The openings include a central opening having a diameter of less than 5 mm. The sampler also includes a liquid containing means and a pump means. The liquid containing means contains a flushing solution, which is expelled through the introduction end by the pump means.

Claim 35 is directed to a method for taking a sample from a body cavity comprising introducing a sampler tube into the entrance of the cavity. The sampler tube includes a tubular means adapted to be introduced in said cavity. A storage means is connected to said tubular means. A vacuum means is connected to the storage means and/or the tubular means. Like claims 20 and 31, claim 35 has been amended to recite that the tubular means has a rigid tube with a fixed outer diameter of at least 1 cm and a curved introduction end. A number of sampling openings is provided only at the curved introduction end. The openings include a central opening having a diameter of less than 5 mm. The sampler tube also includes a liquid containing means and a pump means. The liquid containing means contains a flushing solution, which is expelled through the curved introduction end by the pump means. The sampler tube is moved into the cavity, up into contact with a blind end of the cavity. The flushing solution is expelled into said body cavity. A sample is taken by suctioning the sample at the end of the sampler tube through the openings. Claim 36 depends from claim 35.

B. THE CITED REFERENCES

Ayre is directed to a cytological instrument having a straight tube 5 provided with a scraping and aspiration head 7 and a vacuum means. The tubular means has a diameter of more than 1 cm and opening only at a curved distal end. Specifically, the head 7 is provided with aspiration holes 11 and upstanding ribs 10. One of ordinary skill would understand that the glycerine taught in Ayre is a coating on the interior and exterior of the conically shaped surface 7.⁴ The ribs 10 are formed to scrape cells from a lesion in the vaginal cavity, resulting in desquamation of cells, many of which may then adhere to the coating on the head 7.⁵ The bulb 6 is initially squeezed to expel air from the cytological instrument through the holes 11.⁶ This creates a vacuum when retrieving the instrument from the vaginal cavity, allowing cells scraped from the cervix and desquimated into the mucus from the cervical or uterine lesion to be aspirated into the head 7.⁷

Unlike the recited invention, Ayre does not disclose the presence of a number of side holes 46 including a central sampling opening 47 in a curved introduction end 48 of a rigid tube 44. Ayre's holes 11 are only provided on the conically shaped surface of the head 7 between the ribs 10, not on a curved introduction end. Nor does Ayre disclose a tube having a fixed outer diameter because Ayre's tube has ribs, and therefore has a varying diameter. The dimensions and construction details make the sampler according to the present invention suitable for expelling a flushing solution, closing off a closure in the body cavity, and using a flushing solution to obtain cells from the body cavity in order to allow recollection of the flushing solution with cells.

The Examiner acknowledges that Ayre does not disclose the recited opening that is less than 5 mm in diameter, the vacuum means comprising a pump means, the vacuum means comprising a plunger cylinder, or the tube comprising a cylinder. To overcome these deficiencies, the Examiner cites Suzuki, which is directed to a mucus-removing device for suctioning mucus out of an animal's uterocervical canal because this mucus may interfere

⁴ Ayre at column 2, lines 14-22.

⁵ Ayre at column 2, lines 38-40.

⁶ Ayre at column 2, lines 35-37.

⁷ Ayre at column 2, lines 40-45.

with the collection of embryos. Suzuki's device is intended to introduce the catheter at the tip of the device into an uterocervical canal of an animal, particularly a cow, to suction away mucus from the canal by a vacuum means. Thus, Suzuki is in a different field of endeavor from Ayre and the claimed invention.

The Examiner further acknowledges that Ayre and Suzuki fail to disclose a rigid tube that provides closure in a body cavity for a flushing solution when expelled, and that the tube further comprises a number of sampling openings only at the curved introduction end wherein the sampling openings comprise a central opening. To overcome these failures, the Examiner relies on Mendoza. Mendoza discloses an instrument for artificial insemination for bovines and other animals. The instrument has a tubular shaped distal end with a number of sampling openings only at the curved introduction end. However, a speculum is needed to introduce the instrument in the animal's body cavity. An inflatable balloon surrounding the distal end of the instrument is used to anchor the instrument in the correct position to form a seal with the cervix of the animal's uterus in order to deliver the semen and diluent fluid to the uterus.

C. THE RECITED INVENTION IS PATENTABLE OVER THE CITED REFERENCES

The recited invention is patentable over the cited references because the cited references do not teach a rigid tube having a fixed outer diameter, a flushing solution or an expelling step, and because there is no reason to combine the references in a manner that results in the recited invention and because Suzuki is a non-analogous reference. Notwithstanding these reasons, the secondary evidence submitted with this Amendment rebuts the obviousness rejection.

1. The cited references do not teach a rigid tube having a fixed outer diameter.

According to the Examiner, Ayre discloses a tubular means having a diameter of at least 1 cm. However, Ayre's tubular means does not have a fixed outer diameter because its tubular means has ribs 10 suitable for scraping cells from the vaginal portio of the cervix.⁸ Thus, the diameter of Ayre's tubular means fluctuates. Accordingly, Ayre does not

⁸ Ayre at col. 3, lines 25-28.

teach a tubular means having a fixed outer diameter, and there is no reason to modify Ayre to remove these ribs because doing so would eliminate the function of Ayre's invention – scraping cells from the cervix.⁹ For this reason, Applicants respectfully request that this rejection be reconsidered and withdrawn.

2. The cited references do not teach the recited flushing solution or the recited expelling step.

Applicants respectfully disagree with the Examiner that Ayre teaches a flushing solution and repeat the argument previously presented. When making a rejection under 35 U.S.C. § 103, the Patent Office has the burden of establishing a *prima facie* case of obviousness. *In re Fritch*, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). To establish a *prima facie* case of obviousness, the references must be evaluated based on what each, as a whole, teaches to one of ordinary skill in the art. *In re McLaughlin*, 443 F.2d 1392 (CCPA 1971). To establish this, each and every claimed element must be taught or made obvious by the applied references. *Ex parte Likins*, Application No. 10/010,392, Appeal No. 2004-0760, 2004 WL 4981756 at *3 (BPAI Apr. 8, 2004).

There is no reason or motivation to combine the references in a manner that results in the recited invention. As part of a *prima facie* case, an Examiner must establish some reason to combine the references. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731 (2007); *Takeda Chemical Industries, Ltd. v. Alpharpharm Pty., Ltd.*, 492 F.3d 1350, 1356-1357 (Fed. Cir. 2007). The *KSR* Court acknowledged the importance of identifying a reason that would have prompted a person of ordinary skill in the art to combine the elements in the way the claimed invention does. *KSR Int'l*, 127 S.Ct. at 1731; *Takeda Chemical*, 492 F.3d at 1356-1357. Repeatedly throughout the *KSR* decision, the Court discussed the importance that the result obtained by a particular combination was predictable to one of ordinary skill in the art. *KSR Int'l*, 127 S.Ct. at 1731 and 1739-1742. Mere conclusory statements are insufficient to establish the requisite reason to combine. See MPEP § 2141, citing *In re Kahn* 441, F.3d 977, 988 (Fed. Cir. 2006).

⁹ Ayre at abstract.

As the Declaration previously submitted states, one would not have developed the recited invention by combining these references. Specifically, these references do not teach or suggest how to obtain comfortably a sample at one's house.¹⁰

Due to the lack of the requisite reason to combine these references, the Applicants respectfully request reconsideration and withdrawal of these rejections.

3. Mendoza and Suzuki are non-analogous references.

Applicants respectfully disagree that Mendoza and Suzuki are analogous references and repeat the argument previously submitted.

According to MPEP § 2141.01(a),

The examiner must determine what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue. "Under the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed." *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1397 (2007). Thus a reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole.

In this case, Mendoza and Suzuki do not address similar needs or problems and are from different fields of endeavor. Suzuki is directed to removing mucus from cows after embryogeny.¹¹ This is unrelated to Ayre's and the inventor's field of endeavor – sampling cells from the cervix. Furthermore, Mendoza is directed to a device for artificial insemination – not sampling cells from the cervix.

Viewing Suzuki and Mendoza both as a "sampling device" improperly expands the field of endeavor to include animal veterinary medicine. Since Suzuki is directed to animal veterinary medicine, not gynecology, it is a non-analogous reference.

¹⁰ Declaration by Martinus Antonius Wiegerinck at page 2.

¹¹ Suzuki at abstract.

Since non-analogous references cannot be combined, the Applicants respectfully request reconsideration and withdrawal of these rejections.

4. The secondary evidence rebuts the obviousness rejection.

In his Declaration, Martinus Antonius Wiegerinck, one of the inventors, states that before the disclosure of the recited invention, there were no satisfying solutions to enable one to collect samples from a body cavity in non-medical environment, e.g., a person's home. This long-felt, but unresolved need, has been solved by the recited invention because the sampler has a number of structural features to enable one to collect samples from a body cavity in a non-medical environment, examples of which are described in the Declaration.

Additionally, the Declaration further states that the claimed invention provides the unexpected result that, when the features are combined as such, the invention provides the unexpected result that the samples can be used in a non-medical environment.

Secondary evidence, such as long-felt but unresolved need or unexpected results, rebuts a *prima facie* showing of obviousness.

Response to Office Action

The Examiner improperly discredits the Wiegerinck declaration. It is immaterial whether the declarant has a financial interest in the invention. A declaration should be treated as evidence. Thus, unless there is evidence to the contrary, the Examiner is obligated to accept the statements in the declaration as true.

Furthermore, the Examiner mischaracterizes the declaration. While the declaration states that the declarant is "aware" of the cited references, it also states that "the interpretation of the prior art documents as discussed below is to my best knowledge what a person skilled in the art would learn from those publications."¹²

Moreover, the declarant has not performed piecemeal analysis, because the declarant has considered the references as a whole – he considers the fact that Mendoza is

¹² Wiegerinck Declaration at page 1.
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directed to artificial insemination and Suzuki is directed to mucus-removing devices. As discussed above, these are aspects that, if considered, should lead one not to combine the references. Only the failure to consider these teachings could allow one to combine them.

Thus, in view of the secondary evidence submitted in the Declaration by Martinus Antonius Wiegerinck, it is respectfully requested that the obviousness rejection be reconsidered and withdrawn.

III. REJECTION OF CLAIMS 29, 30, 32 and 37

Claims 29, 30, 32 and 37 have been rejected as purportedly unpatentable over the combination of Ayre, Mendoza, Suzuki and Lurie¹³. These claims ultimately depend from independent claims 20, 31, or 35. Applicants respectfully traverse this rejection for the reasons discussed above, and because Lurie does not overcome any of the above-identified deficiencies.

Furthermore, Lurie is directed to a device for taking samples from a uterus, not a vaginal cavity. Such devices require a thinner catheter to be able to pass the cervical channel, and the construction of such devices is vastly different. Due to these differences, one would not find it obvious to use a vacuum means for retrieving samples from a uterus in a sampler for retrieving samples from the cervix.

IV. REJECTION OF CLAIMS 33 , 34, 38 AND 39

Claims 33, 34, 38 and 39 have been rejected as purportedly unpatentable over the combination of Ayre, Mendoza, Suzuki and Oster¹⁴. These claims ultimately depend from claims 20, 31 or 35. Applicants respectfully traverse this rejection for the reasons discussed above, and because Oster does not overcome any of the above-identified deficiencies.

¹³ United States Patent Number 7,207,951 to Lurie *et al.* ("Lurie").

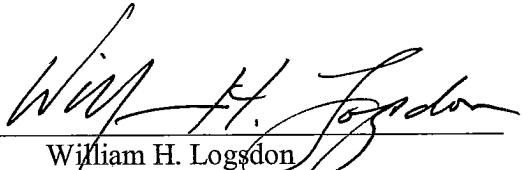
¹⁴ United States Patent Number 3,815,580 to Oster ("Oster").

V. CONCLUSION

In view of the amendments and remarks, Applicants respectfully request that all objections and rejections be reconsidered and withdrawn, and that pending claims 20, 23-29 and 31-39 be allowed. Should the Examiner wish to discuss this matter further, the Examiner is encouraged to contact the Applicants' undersigned representative at (412) 471-8815.

Respectfully submitted,

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